

**REMARKS**

Claims 1-4 are currently pending. No new matter is added by way of this amendment.

**I. Rejection Under 35 U.S.C. § 103(a)**

Claims 1-4 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Publication No. 2003/0211066 to Scholz et al. (hereafter "Scholz") in view of U.S. Patent No. 5,736,547 to Burnier et al. (hereafter, "Burnier"), U.S. Patent No. 5,985,918 to Modak et al. (hereafter "Modak '918"), and U.S. Patent No. 5,965,610 to Modak et al. (hereafter "Modak '610"). Additionally, claims 1-4 stand rejected as obvious over Scholz in view of Burnier, Modak '918 and U.S. Patent No. 6,022,551 to Jampani et al., (hereafter "Jampani").

With regard to the rejection of claims 1-4 as obvious over Scholz in view of Burnier, Modak '918 and Modak '610, the Examiner contends that Scholz describes topical hydroalcoholic compositions comprising an antimicrobial agent (e.g., iodine, chlorhexidine digluconate, triclosan and quaternary compounds), as well as zinc acetate or zinc oxide. The Examiner also alleges that Burnier describes antimicrobial cosmetic compositions comprising synergistic amounts of octoxyglycerin and N-n-octanoylglycine. Additionally, the Examiner states that Modak '918 describes topical compositions comprising zinc stearate and zinc salicylate, or zinc gluconate and zinc acetate, while Modak '610 describes antimicrobial compositions comprising benzalkonium chloride, among other antimicrobial agents, and soluble zinc compounds. According to the Examiner, it would have been obvious to combine the antimicrobial agents of Scholz with the octoxyglycerin of Burnier, and the benzalkonium chloride, first and second zinc compounds described by the Modak references.

With regard to the rejection of claims 1-4 as obvious over Scholz in view of Burnier, Modak '918 and Jampani, the Examiner relies on Scholz, Burnier and Modak '918 as described above. The Examiner further relies upon Jampani for its disclosure of topical compositions comprising benzalkonium chloride. According to the Examiner, it would have been obvious to combine Burnier's octoxyglycerin with the antimicrobials of Scholz, the zinc salts of Modak '918 and the benzalkonium chloride of Jampani.

Applicants respectfully traverse the rejection and request reconsideration. To support an assertion of obviousness, the Examiner must show that "all the claimed elements were known in

the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.” M.P.E.P. § 2143. *See also KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S. Ct. 1727, 82 (2007). Additionally, with regard to the Examiner’s contention that it would have been obvious to combine the various elements of the cited art, Applicants submit that while there are limited circumstances where an obviousness rejection may fairly be based on a contention that the invention was obvious to try, the instant rejection does not fall within those limited circumstances. As noted by the Supreme Court in *KSR v. Teleflex*, 127 S.Ct. 1727, 1739 (2007), it is inappropriate to employ an obvious to try argument in situations where the outcome cannot be reasonably predicted. *See, KSR v. Teleflex*, 127 S.Ct. 1727, 1739 (2007). This distinction between predictable situations where an obvious to try argument is appropriate and unpredictable situations where an obvious to try argument is an inappropriate basis for obviousness was recently clarified further by the Federal Circuit in *In re Kubin*, 561 F.3d 1531 (Fed. Cir. 2009):

In [unpredictable] circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is succinctly encapsulated by the Supreme Court’s statement in *KSR* that where a skilled artisan merely pursues “known options” from a “finite number of identified, predictable solutions,” obviousness under § 103 arises.

*In re Kubin*, 561 F.3d 1531, 1359 (Fed. Cir. 2009).

Applicants respectfully submit that the claims of the present application are not obvious over the cited references because the combined teachings of the references do not suggest or describe all elements of the claims. The pending claims are directed to a composition comprising a first antimicrobial agent consisting of octoxyglycerin and a quaternary ammonium compound (e.g., benzalkonium chloride), wherein the octoxyglycerin and quaternary ammonium compound are present in amounts which exhibit antimicrobial synergy.

In contrast, Scholz, the primary reference, is directed to stable hydroalcoholic compositions which are thickened using mixed emulsifier systems. *See Field of the Invention*. Specifically, Scholz discloses compositions that contain antimicrobials such as iodine, chlorhexidine, triclosan, surfactants with a quaternary group, and silver salts. *See paragraph*

[0156]. Scholz also discloses formulations for barrier creams and lotions to protect against diaper rash, where the formulations may include zinc compounds. Importantly, and contrary to the Examiner's assertions, the zinc compounds are provided for those formulations where creams or lotions are contemplated. See paragraph [0161]. As conceded by the Examiner, Scholz fails to disclose the use of octoxyglycerin, zinc compounds for gel formulations, and a quaternary ammonium compound that works with octoxyglycerin for antimicrobial synergy.

According to the Examiner, the various omitted constituents are provided for in the secondary references. Applicants disagree. Burnier's teachings are limited to the combination of octoxyglycerin and an antimicrobial lipid or hydro lipid. Burnier does not suggest or describe that octoxyglycerin can be combined with any other antimicrobial agents, and in particular, a quaternary ammonium compound, to achieve a synergistic effect. Thus, an artisan of ordinary skill would have no expectation that Burnier's octoxyglycerin could be successfully combined with the quaternary ammonium compound disclosed by Scholz, or the benzalkonium chloride compound disclosed by Modak '610, to achieve a synergistic effect as encompassed by the claims.

Furthermore, Applicants submit that the present claims are directed to a composition that is a hydroalcoholic gel. Modak '610 discloses that only zinc gluconate was able to successfully form a gel matrix when combined with water, alcohol and an antimicrobial (e.g., chlorhexidine gluconate). See, Modak '610 at Col. 7, ll. 24-49. Thus, in view of Modak '610, a skilled artisan seeking to formulate an antimicrobial gel comprising zinc would only seek to formulate such a gel with zinc gluconate. The artisan would have no expectation that other zinc salts, for example, the zinc salicylate, zinc acetate, or zinc stearate of Modak '918, could be successfully incorporated into a hydroalcoholic gel.

As noted above, Applicants note that the Examiner only relies upon Jampani for the ingredient benzalkonium chloride, and as such, Jampani does not cure the other references' deficiencies with regard to antimicrobial synergy or the inclusion of two zinc salts into a hydroalcoholic gel, as discussed above.

Accordingly, Applicants respectfully submit that the claimed invention is not obvious over the cited art and request that the rejections be withdrawn.

## **II. The Double Patenting rejection**

The Examiner has rejected claims 1-4 on the ground of nonstatutory obviousness-type double patenting as double-patenting over claims 1-2, 6, 24-25 and 29 of U.S. Patent No. 6,846,846 ("the '846 patent"). The Examiner contends that the '846 patent is directed to an antimicrobial composition comprising synergistically effective amounts of octoxyglycerin, a quaternary ammonium compound, and an antimicrobial compound selected from a biguanide, triclosan, phenoxyethanol, an iodine compound and parachlorometaxylenol. According to the Examiner, the claims of the instant application are not patentably distinct over the claims of the '846 patent.

Without conceding to the Examiner's contentions, Applicants respectfully submit that the appropriate action will be taken (*e.g.*, through the submission of a Terminal Disclaimer), upon withdrawal of the rejections under 35 U.S.C. § 103(a).

**III. Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and the rejections withdrawn. If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below. Applicants believe no fee in addition to the fee associated with the Request for Continued Examination submitted herewith is due. However, if any other fees are required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit any overpayments made, to Deposit Account 02-4377.

Respectfully submitted,

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